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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,008	04/12/2001	Shinichi Mochizuki	10939/2022	4949

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1653	8

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,008	MOCHIZUKI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Foreign Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on October 28, 1998. It is noted, however, that applicant has not filed a certified copy of the 322874/1998 application as required by 35 U.S.C. 119(b). An English translation of JP 322874/1998 filed May 29, 2001 is acknowledged (Paper No. 4).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bone-pathobolism treating agent comprising osteoclastogenesis inhibitory factor (OCIF), or its variant (OCIF2, OCIF3, OCIF4 or OCIF5) and a polysaccharide such as heparin, dextran sulfate, pectin or carrageenan; or, a bone-pathobolism treating agent comprising OCIF, a defined variant of OCIF, OCIF and a defined polysaccharide, or, an osteoanaplerotic material and a defined polysaccharide as indicated in the prior art, does not reasonably provide enablement for a bone-pathobolism treating agent comprising at least one substance selected from an undefined homolog or variant of OCIF, or, a polysaccharide. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

Claims 1-4 are directed to a bone-pathobolism treating agent comprising at least one substance selected from OCIF, any homolog or any variant, or, a polysaccharide or an unidentified derivative thereof. The specification, however, states that a bone-pathobolism treating agent comprising "both" at least one substance selected from the group consisting of OCIF, its homolog and its variant, and, a polysaccharide or its derivative (page 1, lines 4-9). There are no indicia that the present application enables the full scope in view of a bone-pathobolism treating agent as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is enabled.

The breath of the claims is broad and encompasses unspecified variants regarding the homolog or variant of OCIF, or the derivative of polysaccharide as a bone-pathobolism treating agent, which are not adequately described or demonstrated in the specification.

(2). The absence or presence of working examples:

There are no working examples indicating the claimed variants except for a bone-pathobolism treating agent comprising OCIF and a polysaccharide such as heparin, dextran sulfate, pectin or carrageenan (Examples 1-8; Figs 1-10). The specification has not shown the

use of any homolog or variant of OCIF, or a polysaccharide alone as a bone-pathobolism treating agent. Thus, it is necessary to carry out further experimentation to assess the effects of these compounds.

(3). The state of the prior art and relative skill of those in the art:

The prior art indicates a bone-pathobolism treating agent comprising OCIF, a defined variant of OCIF, OCIF and a defined polysaccharide, or, an osteoanaplerotic material and a defined polysaccharide (Goto *et al.* (1998); Goldenberg *et al.* (1998); Nobuyyki *et al.* (1987)). However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the identity and use of homolog or variant of OCIF, or the derivative of polysaccharide as a bone-pathobolism treating agent to be considered enabling for the claimed variant.

(4). Predictability or unpredictability of the art:

The specification has shown the effect of OCIF on bone-pathobolism can be further increased by adding a polysaccharide to OCIF to form a preparation (pages 2-3). However, the specification does not demonstrate a homolog or variant of OCIF, or a polysaccharide alone is a bone-pathobolism treating agent, the invention is highly unpredictable regarding the effect of the compound used in the treatment. For example, the specification indicates heparin or dextran sulfate can enhance the hypocalcemic effect of OCIF, but the prior art (Chowdhury et al. 1992; Cochran et al., 1988) has shown heparin or other glycosaminoglycans can increase bone resorption. Thus, the art would suggest a different result.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a bone-pathobolism treating agent comprising at least one substance selected from OCIF, its homolog or its variant, or, a polysaccharide or its derivative. The specification indicates certain known variants of OCIF and some known derivatives of polysaccharides can be used for treating bone-pathobolism (pages 3-7), and further indicates the use of OCIF with a polysaccharide such as heparin, dextran sulfate, pectin or carrageenan as a bone-pathobolism treating agent, and the effect of OCIF can be increased by adding a polysaccharide to OCIF (Examples 1-8; Figs 1-10). However, the specification has not demonstrated the use of a homolog or variant of OCIF, or a polysaccharide alone as a bone-pathobolism treating agent. There is no working example demonstrating the bone-pathobolism effects of these compounds. Since the specification fails to provide sufficient guidance on the use and effect of an identified homolog or variant of OCIF, or a derivative of polysaccharide, it is necessary to carry out further experimentation to assess the effects of these compounds.

(6). Nature of the Invention

The scope of the claims encompasses a bone-pathobolism treating agent comprising at least one substance selected from OCIF, its homolog or its variant, or, a polysaccharide or its derivative, but the specification does not demonstrate the use and the effect of the compound. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, the working example does not demonstrate the claimed variants, the art is unpredictable regarding the effects of claimed compounds, and the guidance and the teaching in the specification are limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of the compounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1-5 are indefinite because of the use of the term "at least one substance selected from the group.....its derivatives". The term "at least one substance selected from the group.....its derivatives" renders the claim indefinite, it is not clear whether the agent comprises an OCIF with a polysaccharide, or, an OCIF, or a polysaccharide. It is also not clear what compound the derivative is, and how different the derivative is from the parent compound. Claims 2-4 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

5. Claim 3 is indefinite because of the use of the term "and/or". The term "and/or" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and".

6. Claim 5 is indefinite because the claim lacks essential steps as claimed in the process of enhancing the activity of osteoclastogenesis inhibitory factor. The omitted steps are at least the effective amount of the polysaccharide used and the outcome of the method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Goto *et al.* (EP 0816380, January 7, 1998).

Goto *et al.* teach an osteoclastogenesis inhibitory factor (OCIF) isolated from human embryonic lung fibroblast, and its variants such as OCIF2, OCIF3, OCIF4 and OCIF5 have the activity of inhibiting differentiation and/or maturation of osteoclasts (page 2, lines 48-52; page 3, line 22, 51-57; claims 1 and 2). In addition to the property of inhibiting differentiation and/or maturation of osteoclasts, OCIF or its variant also has the inherent property of reducing calcium concentration in serum, thus OCIF or its variant is a bone-pathobolism treating agent.

8. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Goldenberg *et al.* (WO 98/46211, October 22, 1998).

Goldenberg *et al.* teach a sustained-released composition containing a biological active agent such as osteoprotegerin (page 11, line 16; known as osteoclastogenesis inhibitory factor; claim 1), a hydrophilic polymer such as dextran sulfate, heparin or carrageenan (page 7, lines 24-page 8, line 17; claims 3 and 4), and at least one precipitating agent (page 5, line 23-page 6, line 1). The OCIF in the composition has the inherent property of reducing calcium concentration in serum, thus, it is a bone-pathobolism treating agent.

9. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Nobuyyki *et al.* (JP 62-201825, September 1987, abstract).

Nobuyyki *et al.* teach a remedy for osteopathy which has bone resorption-suppressing and bone calcification activities comprises a calcification promoting agent such as chondroitin sulfate, heparin, hyaluronic acid or dextran sulfate, and a water soluble osteoanaplerotic material such as hydroxyapatite (claims 1, 3 and 4).

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CHRISTOPHER S. F. LOW
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February 4, 2003